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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/728,275 | 12/04/2003 | Atul Varadhachary | HO-P02726US2 | 7126 |

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| EXAMINER | |
|---|---|
| ROBINSON, HOPE A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/728,275 | VARADHACHARY ET AL. | |
| | Examiner | Art Unit | |
| | Hope A. Robinson | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/27/04, 7/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Application Status*

1. Applicant's election without traverse of Group I (claims 1-31) on December 22, 2004 is acknowledged. Claims 32-34 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

### *Specification*

2. The specification is objected to because of the following informalities:

The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as ZOCOR®, LESCO®, ZETIA®,for example, have been noted in this application (see pages 2, 9 and 25). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Correction is required.

### *Drawing*

3. The drawings filed on December 4, 2003 have been accepted by the examiner.

***Information Disclosure Statement***

4. The Information Disclosure Statements filed on February 27, 2004 and July 29, 2004 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

***Claim Rejections - 35 USC ∋ 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-2 and 11-31 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 1 is indefinite for the recitation of "provide an improvement in the cardiovascular disease in a subject" because it is unclear how the administration of the composition improves the disease state, does it cure the disease or reduce symptoms? How does it make the disease more manageable or improve it. The dependent claims hereto are also included in this rejection because they do not rectify the deficiency.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cianflone et al. (Atherosclerosis, vol. 120, 1996, pages 101-114), based on the broad recitation of administration of lactoferrin.

Cianflone et al. teach the administration of lactoferrin which results in the inhibition of LDL receptor related protein interaction and HTg-VLDL increases in intracellular cholesterol ester in a subject (claim 3), said administration by Cianflone et al. would result in improvement in cardiovascular disease in said subject as the claimed method (see claim 1) only requires administration of lactoferrin to produce this effect. The fact that administration of lactoferrin results in treating a cardiovascular disease, and Cianflone et al. administers lactoferrin, claim 2, which recites atherosclerosis, is anticipated as this is inherent. The composition taught by Cianflone et al. has a carrier (claim 10) and a human lactoferrin (claims 11 and 12), see pages 101-102, 109 and 112 of the reference. Therefore, the limitations of the claims are met by the reference.

***Claim Rejections - 35 USC ∋ 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

8. Claims 1-12, 14,17-19 and 26 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Nuijens et al. (U.S. Patent No. 6,333,311, February 3, 1993).

Nuijens et al. teach the production of a composition containing human lactoferrin and lactoferrin variants administered to patients to reduce inflammation after myocardial infarction (claim 1, see columns 1-2). Nuijens et al. disclose the human lactoferrin (claims 11-12, see column 1) or variants thereof (claim 14, see columns 1-2) are useful

for treatment of human diseases and conditions including inflammation (claim 5). In addition, Nuijens et al. disclose that lactoferrin is useful for the treatment of anemia, myelopoieses, reducing reperfusion injury, cytokine release (claim 26) and proteoglycan-mediated entry of virus cells (column 5). The composition of Nuijens et al. comprises a carrier (claim 10, see column 1 of the patent). Although Nuijens et al. does not explicitly teach a treatment of cardiovascular disease, for example, atherosclerosis or reduction of LDL/VLDL (claims 2-3) or increase levels of HDL (claim 4) or reduce circulating C-reactive protein (claim 6) or reduce proliferation of vascular smooth muscle cells (claim 7) or reduce vascular spasm (claim 8) or promote endothelial integrity (claim 9) the patent discloses lactoferrin in a composition administered to patients and the instant claims broadly recite administration of lactoferrin, therefore, the administration of the same composition by Nuijens et al. would necessarily produce the same results which is the treatment of cardiovascular disease, such as atherosclerosis, the reduction of LDL/VLDL or increased levels of HDL and the results cited in claims 6-9. The reference also teaches that the pharmaceutical compositions can be administered intravenously (claims 17-18, see column 14) or orally (claim 19, see column 14) or intradermal or intramuscular.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have a method of treating a cardiovascular disease comprising the step of administering to a subject a lactoferrin composition wherein the cardiovascular disease is atherosclerosis and the lactoferrin composition once administered results in a decrease in the LDL/VLDL levels or an increase in HDL

levels or produce the results cited in claims 6-9, because Nuijens et al. teach a method to treat human diseases and conditions with a lactoferrin composition by administering lactoferrin or a variant thereof intravenously (parenterally) or orally. The instant specification indicates that lactoferrin is useful in treating vascular inflammation and the Nuijens et al. patent reports the treatment of inflammation following myocardial infarction (column 2) and the affect of lactoferrin on cytokine release (column 5). Although the reference is silent on "cardiovascular disease", one of ordinary skill in the art knows that if a composition is the same once administered to a patient will necessarily produce the results as claimed absent evidence to the contrary. Moreover, the method as claimed has only one step, to administer a lactoferrin composition, the intended use differs from the patent, however, the composition administered is the same and once administered would produce the same results. Thus, the claimed invention was obvious to make and use at the time it was made and was *prima facie* obvious.

## ***Conclusion***

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-

0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS
Patent Examiner 3/16/05